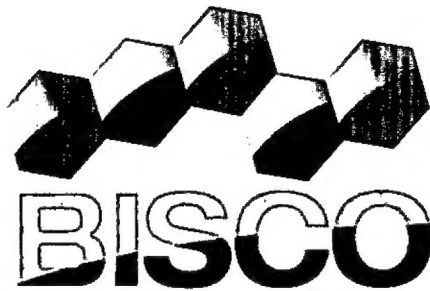


K123653



JUN 03 2013

510 (k) SUMMARY

Applicant: Bisco, Inc.
1100 W. Irving Park Road
Schaumburg IL, 60193

Contact Person: Michelle Schiltz-Taing
Tel: 847-534-6146
Fax: 847-534-6146

Date Prepared: 24 April 2013

Trade Name: **Seal Block**

Common Name: Tooth Desensitizer

Product Code: LBH

Classification/Name: Varnish, Cavity
Class II per 21 CFR 872.3260

Predicate Devices:

Seal Block is substantially equivalent to:

BisBlock by Bisco, Inc. Schaumburg IL K033521
Super Seal by Phoenix Dental, Inc. Fenton, MI K983477
Super Seal Tooth Desensitizer by Phoenix Dental, Inc. Fenton, MI K120109

Indications for Use Seal Block PRO Version:

The indication for use of Seal Block PRO is to relieve sensitive teeth.

Seal Block PRO is used to relieve sensitive teeth by blocking the pain caused by:

- Hot
- Cold
- Sweet
- Acidic
- Dental whitening agents

Seal Block PRO can also be used to relieve sensitivity:

- Prior to temporization (placement of provisional restorations).
- Prior to permanent cementation of indirect restorations.
- Prior to placement of direct restorations.
- When root surfaces are exposed.



510 (k) SUMMARY (continued)

Indications for Use Seal Block OTC Version:

Seal Block relieves sensitive teeth by blocking the pain caused by: heat, cold, sweets, acidic foods and drinks, dental whitening agents.

Description of Applicant Device:

Seal Block is applied using an applicator to the sensitive tooth/teeth. It forms calcium oxalate crystals that occlude dentinal tubules resulting in desensitization of natural dentition.

Technological Characteristics:

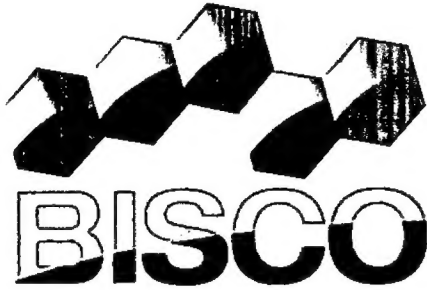
All components of Seal Block are based upon industry standard chemistry and are found in the legally marketed predicate devices Super Seal (K983477 and K120109) and BisBlock (K033521). Comparisons of the chemical composition of Seal Block to the predicates are provided in the following table:

Chemical Composition	Super Seal K983477	Super Seal Tooth Desensitizer K120109	BisBlock K033521	Seal Block Pro and OTC
Oxalate Solution	X	X	X	X
Water Based	X		X	X

Performance Data:

The physical/mechanical properties of Seal Block were tested in the lab using R&D testing protocols to determine dentin permeability reduction, shear bond strength, and pH. The information provided in this 510(k) for Seal Block compared to the predicates demonstrates that it is effective for its indications of use. A comparison of the physical/mechanical properties are included below:

Physical / Mechanical Property Comparison	Super Seal K983477	Super Seal Tooth Desensitizer K120109	BisBlock K033521	Seal Block
Low viscosity	X	X	X	X
SEM Comparison	X		X	X



510 (k) SUMMARY (continued)

Biocompatibility:

An evaluation of biocompatibility was conducted to determine the safety of Seal Block. It is concluded from the safety evaluation and the results of the ADA Oral Toxicity Study (10 rats, 14 days) that Seal Block is safe for its intended uses.

Conclusion:

Side by side comparisons clearly demonstrate that the applicant device is substantially equivalent to the other legally marketed devices. It is concluded that the information supplied in this submission has proven the safety and efficacy of these products.



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center - WO66-G609
Silver Spring, MD 20993-0002

June 3, 2013

Ms. Michelle Schiltz-Taing
Bisco, Incorporated
1100 West Irving Park Road
SCHAUMBURG IL 60193

Re: K123653

Trade/Device Name: Seal Block OTC, Seal Block Pro
Regulation Number: 21 CFR 872.3260
Regulation Name: Cavity Varnish
Regulatory Class: II
Product Code: LBH
Dated: April 24, 2013
Received: May 9, 2013

Dear Ms. Schiltz-Taing:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.


If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address <http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm>. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to <http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm> for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address <http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm>.

Sincerely yours,


Digitally signed by Mary S. Runner -S
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ou=FDA, ou=People, cn=Mary S. Runner -S,
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Kwame Ulmer, M.S.
Acting Division Director
Division of Anesthesiology, General Hospital,
Respiratory, Infection Control and
Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

510 (k) Number (if known): K123653

Device Name: Seal Block Pro

Indications for Use:

The indication for use of **Seal Block PRO** is to relieve sensitive teeth.

Seal Block PRO is used to relieve sensitive teeth by blocking the pain caused by:

- Hot
- Cold
- Sweet
- Acidic
- Dental whitening agents

Seal Block PRO can also be used to relieve sensitivity:

- Prior to temporization (placement of provisional restorations).
- Prior to permanent cementation of indirect restorations.
- Prior to placement of direct restorations.
- When root surfaces are exposed.

Prescription Use ☒ AND/OR Over-The-Counter Use ☐
(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

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IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

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(Division Sign-Off)
Division of Anesthesiology, General Hospital
Infection Control, Dental Devices

510(k) Number: K123653

510 (k) Number (if known): K123653

Device Name: Seal Block OTC

Indications for Use:

Seal Block relieves sensitive teeth by blocking the pain caused by: heat, cold, sweets, acidic foods and drinks, dental whitening agents

Prescription Use ☐
(Part 21 CFR 801 Subpart D)

AND/OR

Over-The-Counter Use ☒
(21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE
IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

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(Division Sign-Off)
Division of Anesthesiology, General Hospital
Infection Control, Dental Devices

510(k) Number: K123653